

**ENTERED**

January 04, 2017

David J. Bradley, Clerk

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF TEXAS  
HOUSTON DIVISION**

ANNE S. TSAO, M.D.,  
Plaintiff,

vs.

FERRING PHARMACEUTICALS, INC.,  
Defendant.

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CIVIL ACTION NO. 4:16-CV-01724

**AMENDED MEMORANDUM AND RECOMMENDATION ON  
DEFENDANT’S MOTION TO DISMISS PLAINTIFF’S COMPLAINT**

This matter was referred by United States District Judge Vanessa D. Gilmore, for full pre-trial management, pursuant to 28 U.S.C. § 636(b)(1)(A) and (B). (Docket Entry #14). Defendant, Ferring Pharmaceuticals, Inc. (“Defendant” “Ferring”) has filed a Motion to Dismiss, under Rule 12 (b) (6), for failure to state a claim upon which relief can be granted, and Rule 9 (b), for failure to meet the heightened pleading requirements for claims of fraud. (Docket Entry #11). Plaintiff, Anne S. Tsao (“Plaintiff” “Tsao”) filed a Response in Opposition to the Motion to Dismiss. (Docket Entry #15). Defendant responded with a Reply in Support of its Motion. (Docket Entry #16). Both parties objected to that memorandum and recommendation. (See, Plaintiff’s Objections to Memorandum and Recommendations, Docket Entry #22, Defendant’s Objections to Memorandum and Recommendations, Docket Entry #21). In deference to Plaintiff’s objections, the following Amendments to that recommendation, reflected in bold typeface, have been made. After considering the pleadings and the applicable law, it is **RECOMMENDED** that Defendant’s Motion be **GRANTED** in part, and **DENIED** in part.

### **BACKGROUND**

Tsao seeks recovery for injuries and damages she contends resulted from her use of a prescription fertility drug, Bravelle. Unlike most claims involving prescription drug use, Tsao does not allege that she suffered an adverse side effect, or that there were inadequate warnings for known side effects. Instead, Tsao complains the fertility drug simply did not work, because it was not as potent as advertised.

Ferring Pharmaceuticals, Inc. manufactured Bravelle, a fertility medicine, from 2002 until it was voluntarily recalled in October of 2015. (Plaintiff's Original Complaint at 5, 12, 17, 33, Defendant's Motion to Dismiss at 4). Bravelle was used to treat women in need of help to develop and release ovarian eggs. (Plaintiff's Original Complaint at 3). It was also used to develop and release more than one egg at a time, as part of an Assisted Reproductive Technology cycle, such as in vitro fertilization ("IVF"). (*Id.* at 3, 5).

In August of 2014, Plaintiff began the first, of seven, in vitro fertilization cycles under the direction of her doctors. (*Id.* at 5-6). The in vitro process was initiated with a two to three week course of Bravelle injections to stimulate egg development. (*See, e.g., id.* at 4-5). Plaintiff's last course of Bravelle fertility treatments took place in October of 2015. (*Id.* at 8, 17). The total cost of the IVF treatment was more than \$120,000.00, and \$19,246.40 of that cost was for the Bravelle injections. (*Id.* at 14-17).

Ferring initiated a voluntary recall of Bravelle in October of 2015, because internal testing showed diminished potency in certain lots, which resulted in decreased therapeutic effect. (*Id.* at 7). Plaintiff alleges that she used the affected lots of Bravelle during each of her IVF cycles. (*Id.*

at 8). Plaintiff implies, but does not articulate, that the reduced potency of the affected lots caused the failure of her IVF cycles.<sup>1</sup> (*Id.* at 17).

Tsao lodges three causes of action against Ferring. First, she alleges that Defendant's sale of the Bravelle lots with reduced potency violated several provisions of the Texas Deceptive Trade Practices Consumer Protection Act ("DTPA"), TEX. BUS. & COM. CODE ANN. §§ 17.41-17.63, et. seq. (West 2005). (*Id.* at 10-12). Specifically, Plaintiff claims that Ferring falsely represented the quantity of the active ingredient in Bravelle; that it misrepresented the quality of Bravelle; that it advertised Bravelle with the intent to sell a different product; and that it failed to disclose negative information about Bravelle so that she would buy the medication. (*Id.* at 11, see also, TEX. BUS. & COM. CODE § 17.46(b)). Next, she alleges that Ferring breached an implied warranty of merchantability, because the affected lots of Bravelle were unfit for their intended purpose, and were not of merchantable quality. (*Id.* at 12-13). Finally, Tsao makes a claim for the breach of an express warranty, because the affected lots of Bravelle did not have the potency claimed in the literature the company provided. (*Id.* at 13-14). Tsao insists that Ferring's violations of the DTPA were committed knowingly and intentionally, and so she is entitled to treble damages, as well as damages for her mental anguish. (*Id.* at 11, 17).

Defendant seeks dismissal of each of these causes of action under Federal Rules of Civil Procedure 8, 9(b), and 12(b)(6). (Defendant's Motion to Dismiss at 2). It first argues that all of Plaintiff's claims should be dismissed, because she has not alleged that Bravelle actually failed to work for her, and so she has failed to set out a valid cause of action. (*Id.* at 6). Ferring contends that

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<sup>1</sup> Plaintiff's Complaint does not allege explicitly that all seven rounds of IVF failed, or that the failure was caused by the reduced potency of Bravelle. She claims only that she underwent "fertility treatments that were destined to fail." (Plaintiff's Original Complaint at 17). Her Complaint does strongly support the inference, however, that the IVF treatments failed. (*Id.* at 6, 14-17).

Plaintiff has unwittingly pleaded herself out of court, because her allegations contradict any theory that Bravelle did not, in fact, work for her. (*Id.* at 7). To support this contention, the Company points to Plaintiff's contention that it "warranted that the Affected Lots contained FSH in sufficient amount and with sufficient potency to treat women who need help developing and releasing eggs as well as those with healthy ovaries to make multiple eggs. . . ." (*Id.*). Ferring points out that Plaintiff has not alleged that she did not ovulate or produce multiple eggs after using the complained of medicine. (*Id.* at 7). Ferring argues that Tsao has failed to plead that the reduced potency of the drug caused any injury to her, a basic element of any cause of action. (*Id.* at 7-8). Ferring bolsters this argument by pointing out that Plaintiff used Bravelle, then underwent egg retrieval, and in vitro fertilization on seven different occasions. (*Id.* at 7-8). Defendant argues that this shows that Bravelle must have worked, for had it failed Tsao, there would have been no eggs to retrieve. (*Id.* at 8).

Ferring also contends that Tsao has failed to meet the heightened pleading requirements of Rule 9(b) which applies to all causes of action involving fraud, including claims under the DTPA. Ferring argues, specifically, that Tsao has not alleged with sufficient particularity any actionable misrepresentations or false statements. (*Id.* at 10-13). Defendant further claims that Plaintiff's allegations that she relied on a false representation are implausible in the absence of any actionable misrepresentations. (*Id.* at 13). Finally, Ferring argues that Tsao has not pleaded any facts to support her contention that Defendant's alleged misconduct was knowing or intentional. (*Id.* at 14-15). Ferring argues, then, that Tsao's claims for treble damages and mental anguish damages under the DTPA should be dismissed. (*Id.*).

## **STANDARD OF REVIEW**

### **A. Rule 12(b)(6)**

In ruling on a motion to dismiss an action under Rule 12(b)(6) of the Federal Rules of Civil Procedure, the court must accept the allegations as true, view them in a light most favorable to the plaintiff, and draw all inferences in her favor. *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498 (5th Cir. 2000); *Lowrey v. Texas A&M Univ. Sys.*, 117 F.3d 242, 246-47 (5th Cir. 1997). The motion must be denied unless it appears to a certainty that the plaintiff can prove no set of facts that would entitle her to relief. *Hishon v. King & Spalding*, 467 U.S. 69, 73, 104 S.Ct. 2229, 81 L.Ed.2d 59 (1984); *Conley v. Gibson*, 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957); *Collins*, 224 F.3d at 498. Although Rule 12(b)(6) is a powerful tool that can expedite the judicial process and excise court calendars of cases in which there are no judicially cognizable claims, it is a disfavored motion and is granted sparingly. *See Collins*, 224 F.3d at 498; *Clark v. Amoco Prod. Co.*, 794 F.2d 967, 970 (5th Cir. 1986). Generally, in considering a motion to dismiss for failure to state a claim, a district court must limit its inquiry “to the facts stated in the complaint and the documents either attached to or incorporated in the complaint.” *Lovelace v. Software Spectrum, Inc.*, 78 F.3d 1015, 1017 (5th Cir. 1996).

A Rule 12(b)(6) dismissal is not warranted merely because the court believes that the complainant is unlikely to prevail on the merits. *See Scheuer v. Rhodes*, 416 U.S. 232, 236, 94 S.Ct. 1683, 40 L.Ed.2d 90 (1974). “The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims.” *Id.* Even if it appears “almost to a certainty to the court that the facts alleged cannot be proved to support the legal claim,” the suit may not be dismissed if the complaint indeed states a claim. *Mahone v. Addicks Util. Dist. of Harris*

*County*, 836 F.2d 921, 927 (5th Cir. 1988). Dismissal is proper, however, if the complaint does not allege an element that is required to obtain relief. *See Blackburn v. City of Marshall, Tex.*, 42 F.3d 925, 931 (5th Cir. 1995). In weighing the sufficiency of the pleadings, it must be emphasized that “conclusory allegations or legal conclusions masquerading as factual conclusions will not suffice to prevent a motion to dismiss.” *Id.*; and *see Collins*, 224 F.3d at 498.

**B. The DTPA and Rule 9(b)**

The Federal Rules of Civil Procedure dictate that “in all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity.” FED. R. CIV. P. 9(b). The particularity required by “Rule 9(b) necessarily differs with the facts of each case.” *Guidry v. Bank of LaPlace*, 954 F.2d 278, 288 (5th Cir. 1992). Rule 9(b) requires the plaintiff to allege “the particulars of ‘time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what [that person] obtained thereby.’” *Tel-Phonic Services, Inc. v. TBS Int’l, Inc.*, 975 F.2d 1134, 1139 (5th Cir. 1992) (citation omitted). “Claims alleging violations of the Texas Insurance Code and the Deceptive Trade Practices Act . . . are subject to the requirements of Rule 9(b).” *Frith v. Guardian Life Ins. Co. of America*, 9 F.Supp.2d 734, 742-43 (S.D. Tex. 1998). *See also, Patel v. Holiday Hospitality Franchising, Inc.*, 172 F. Supp. 2d 821, 824-25 (N.D. Tex. 2001)(“[C]laims alleging violations of the DTPA are subject to the requirements of Rule 9(b).”).

**DISCUSSION**

A claim has facial plausibility if the plaintiff alleges facts sufficient to allow the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 557, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). The plausibility

standard is not a “probability requirement,” but it does demand more than a sheer possibility that a defendant has acted unlawfully. *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 1949, 173 L.Ed. 2d 868 (2009)(citing *Twombly*, 550 U.S. at 556, 127 S.Ct. 1955). In support of its motion, Defendant has attached a copy of the Patient Information form and Prescribing Information sheet. Generally, in considering a motion to dismiss, under Rule 12(b)(6), the court “must limit itself to the contents of the pleadings, including attachments thereto.” *Collins*, 224 F.3d at 498. If the court is presented with matters outside of the pleadings and does not exclude them, “the motion must be treated as one for summary judgment [and] ... [a]ll parties must be given a reasonable opportunity to present all the material that is pertinent to the motion.” FED. R. CIV. P. 12(d); see *In re Katrina Canal Breaches Litig.*, 495 F.3d 191, 205 (5th Cir. 2007). However, the Fifth Circuit has recognized “one limited exception” to this rule. *Scanlan v. Tex. A & M Univ.*, 343 F.3d 533, 536 (5th Cir. 2003). Under that exception, “documents that a defendant attaches to a motion to dismiss are considered part of the pleadings if they are referred to in the plaintiff’s complaint and are central to her claim.” *Collins*, 224 F.3d at 498–99 (quoting *Venture Assocs. Corp. v. Zenith Data Sys. Corp.*, 987 F.2d 429, 431 (7th Cir. 1993)). For a document to be incorporated into the pleadings under this exception, then, it must (1) be attached to a defendant’s motion to dismiss, (2) referred to in the plaintiff’s complaint, and (3) is central to the plaintiff’s claims.

The Patient Information form and Prescribing Information materials have been directly referenced in Tsao’s Complaint, and are central to her breach of warranty and DTPA claims, because they contain the statements on which her claims are based. It is appropriate then to consider these materials in deciding Defendant’s motion.

A. Breach of Implied Warranty

Tsao alleges that Ferring's conduct in advertising and selling Bravelle breached the implied warranty of merchantability. An implied warranty is a representation about the quality or suitability of a product, and the law implies such a warranty in every contract, "in view of all facts and circumstances attending the transaction, including the nature of the property, terms of the agreement, and trade usages." *American Tobacco Co., Inc. v. Grinnell*, 951 S.W.2d 420, 435 (Tex. 1987). In addition, this implied warranty is codified in the Texas Business and Commerce Code at §§ 2.314 & 2.315. *Polaris Indus., Inc. v. McDonald*, 119 S.W.3d 331, 336 (Tex.App.–Tyler 2003, no pet.). To prevail on a claim for breach of an implied warranty, Tsao must prove that: (1) Ferring sold goods; (2) that the goods were unmerchantable; (3) that she notified Ferring of the breach; and (4) that she suffered injury as a result of the breach. TEX. BUS. & COM. CODE ANN § 2.314 cmt. 13; *Omni USA, Inc. v. Parker–Hannifin Corp.*, 964 F.Supp.2d 805, 816 (S.D. Tex. 2013) (citing *Hartford v. Lyndon–DFS Warranty Servs., Inc.*, No. 01–08–00398–CV, 2010 WL 2220443, at \*11 (Tex.App.–Houston [1st Dist.] May 28, 2010)). To support a claim of unmerchantability, Tsao must show that the goods at issue were defective at the time they left the manufacturer's or seller's possession. *Omni*, 964 F.Supp.2d at 816 (citing *Plas–Tex, Inc. v. U.S. Steel Corp.*, 772 S.W.2d 442, 444 (Tex. 1989)). However, "a product which performs its ordinary function adequately does not breach the implied warranty of merchantability merely because it does not function as well as the buyer would like, or even as well as it could." *General Motors Corp. v. Brewer*, 966 S.W.2d 56, 57 (Tex. 1998).

The Texas Business & Commerce Code provides a nonexclusive list of the minimum criteria required for a product to be deemed unmerchantable. First, a product is considered to be



unmerchantable if it cannot pass without objection in the trade. TEX. BUS. & COM. CODE ANN § 2.314(b)(1). To pass without objection, a product must be of a quality comparable to other products that are sold in that line of trade under the contract description. *Harris Packaging Corp. v. Baker Concrete Constr. Co.*, 982 S.W.2d 62, 65–66 (Tex.App.–Houston [1st Dist.] 1998, pet. denied) (plaintiff did not show that other manufacturers of similar goods placed warning label on their product); *Fitzgerald v. Caterpillar Tractor Co.*, 683 S.W.2d 162, 163–64 (Tex.App.–Fort Worth 1985, writ ref’d n.r.e.)(defendant established the design of forklift sold to plaintiff was the same design used by all manufacturers throughout the world). Second, a product is considered to be unmerchantable if it is unfit for its ordinary purposes. TEX. BUS. & COM. CODE ANN. § 2.314(b)(3) (Vernon 1994). For a product to be unfit for ordinary purposes, it must have a defect, or lack something necessary to its adequacy. *Plas-Tex, Inc.*, 772 S.W.2d at 444. A product is said to “lack something necessary for adequacy” if it does not accomplish the purposes for which it was manufactured, or if it is constructed in a manner which makes it “unreasonably dangerous.” *See, e.g., Hyundai Motor Co. v. Rodriguez*, 995 S.W.2d 661, 665 (Tex.1999)(design of car’s restraint system that caused passenger to be thrown into the roof was unfit for its ordinary purpose); *Church & Dwight Co., Inc. v. Huey*, 961 S.W.2d 560, 569 (Tex.App.–San Antonio 1997, pet. denied)(substance to remove paint was not fit for its ordinary purpose because it could not be rinsed away). And finally, a product is considered unmerchantable if it does not conform to the promises or affirmations of fact which are on the product’s container or label. TEX. BUS. & COM. CODE ANN. § 2.314(b)(6).

If a product is found to be unmerchantable, a plaintiff must then also show that the defect caused her to suffer injury. *Rodriguez*, 995 S.W.2d at 667–68. If she can do so, she may recover

actual damages. Actual damages include direct damages, which are measured by the difference between the value of the goods accepted, and the value of the goods if they had been as warranted. *See* TEX. BUS. & COM. CODE ANN. § 20714(b) (Vernon 1994); *Signal Oil & Gas Co. v. Universal Oil Prods.*, 572 S.W.2d 320, 327 (Tex. 1978).

Accepting Tsao's allegations as true, and construing them in the light most favorable to her, she has satisfied her burden to set out a "short and plain statement of the claim showing [that she] is entitled to relief" on the claim for a breach of an implied warranty of merchantability. Fed. R. Civ. P. 8(a)(2). Tsao purchased and used Bravelle. She paid \$19,246.40 for the medication. Ferring represented in the Prescribing Information that the medication would deliver 75 International Units of FSH when reconstituted. According to Tsao, testing revealed that the drug deteriorated over time, so that each vial of Bravelle that she used delivered less than the promised amount of FSH when reconstituted, reducing its effectiveness or requiring additional doses to obtain the desired effect. (*Id.* at 7-9). Tsao's overarching complaint is that her use of the drug did not result in the birth of a child.

Ferring does not dispute the accuracy of these allegations. Instead, it argues only that Tsao was not injured, because while she claims that the medicine failed to work for her, one can infer that it did indeed work. In support of this argument, Ferring points to evidence that Tsao completed the IVF process, including implantation of eggs, seven times. **Certainly whether the drug worked as intended invokes questions of fact and expert testimony more properly addressed in a motion for summary judgment. Even so, Plaintiff insists that the drug did not work for her, and that allegation is taken as true for purposes of her motion. Even had the medicine worked as intended,** under Texas law, goods that vary from the description or promises on the label, or that

are inadequately labeled, will be said to breach the implied warranty of merchantability for which actual damages are recoverable. TEX. BUS. & COM. CODE ANN. §2.314(b)(b); *see, Riverside Chemical Co. v. Hanson*, 567 S.W.2d 880, 882 (Tex.Civ.App.–Waco 1978, no writ) (allowing breach of implied warranty claim to proceed because mislabeled pesticide caused injury to cattle); *compare, The Knit With v. Knitting Fever, Inc.*, 2011 U.S. Dist. LEXIS 34233, 2011 WL 1161716 (E.D. Pa. Mar. 30, 2011) (suit including breach of implied warranty claim for yarn that did not contain the amount of cashmere stated on the label).

Here, Tsao contends that the Bravelle she used was less potent than what was described, and promised, in the accompanying literature. In other words, the medicine was mislabeled, and Tsao did not get what she paid for, nor did it work. She claims to have suffered economic loss as a result of purchasing the ineffective medication. **With these allegations, Tsao has stated a claim for a breach of an implied warranty that resulted in, at a minimum, economic harm, in that she purportedly purchased more medicine than necessary because it did not contain the level of FSH listed in the Prescribing Information.** Tsao's complaint sets out sufficient facts to make a plausible claim that Ferring's conduct breached the implied warranty of merchantability and caused her injury.

The Complaint also broadly alleges a breach of the implied warranty because the medicine was unfit for its intended use. This appears to be a claim for breach of the implied warranty of fitness for a particular purpose. *See, e.g., Coghlan v. Wellcraft Marine Corp.*, 240 F.3d 449 (5th Cir. 2001). However, such a warranty does not arise unless the particular purpose for which the item was purchased differs from the usual and ordinary use of the goods. *Id.*; *Deeds v. Whirlpool Corp.*, 2016 WL 6070552, \*12 (S.D. Tex. October 17, 2016)(slip copy) In this instance, Bravelle was used

for its ordinary purpose, fertility treatment, and so that warranty is inapplicable. For that reason, Plaintiff has not stated a claim for a breach of the implied warranty of fitness for a particular purpose.

*B. Breach of Express Warranty*

Plaintiff additionally claims a breach of an express warranty in connection with her purchase and use of Bravelle. Texas recognizes both a common law cause of action and a statutory cause of action for the breach of an express warranty. *Superior Broadcast Prod's v. Doud Media Group, L.L.C.*, 392 S.W.3d 198, 207 (Tex.App.–Eastland 2012, no pet.) (noting that the DTPA is not the sole remedy for breach of warranty claims, but the statute does provide additional remedies for the common law claims). Plaintiff contends her breach of warranty claim is governed by the Uniform Commercial Code (“UCC”). (Plaintiff’s Complaint at 13). Article 2 of the UCC, which governs the sale of goods, was adopted in Texas as Chapter 2 of the Business and Commerce Code. *Mehler Technologies, Inc. v. Monolithic Constructors, Inc.*, Civ. A. No. 3:09–cv–0655–M, 2009 WL 3149383, \*3 & n. 17 (N.D. Tex. Sept. 29, 2009), citing *Emerson Elec. Co. v. American Permanent Ware Co.*, 201 S.W.3d 301, 310 (Tex.App.–Dallas 2006, no pet.). Separately, Tsao also claims a breach of the express warranty under the DTPA. (Plaintiff’s Complaint at 11). Although the DTPA allows a consumer to pursue a breach of warranty claim, the act itself does not create any warranties. It merely codifies provisions of the UCC and provides for additional remedies. *La Sara Grain Co. v. First Nat. Bank of Mercedes*, 673 S.W.2d 558 (Tex. 1984). For that reason, Plaintiff’s claims for a breach of warranty under the DTPA and the UCC are treated as one for purposes of Defendant’s motion. *See, e.g., Ketter v. ESC Medical Systems, Inc.*, 169 S.W.3d 791, 796 (Tex.App.–Dallas 2005, no pet) (“[T]here is no relevant distinction between Ketter’s UCC and DTPA

breach-of-warranty claims . . . Accordingly, we will not distinguish between the UCC and DTPA in our discussion of the breach of warranty causes of action.”); *but see, Emerson Elec. Co.*, 201 S.W.3d at 318 (“The breach of warranty question was based on the UCC, as reflected by the proximate cause element in the question, and APW did not request a question on producing cause to support a DTPA warranty theory.”).

Section 2.313 of the Texas Business and Commerce Code, titled “Express Warranties by Affirmation, Promise, Description, Sample,” states that,

(a) Express warranties by the seller are created as follows:

(1) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.

(2) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.

(3) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

(b) It is not necessary to the creation of an express warranty that the seller use formal words such as “warrant” or “guarantee” or that he have a specific intention to make a warranty, but an affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty.

A seller who makes a statement of fact, promise, or description to the buyer, which relates to the goods, and which becomes part of the basis of the bargain, creates an express warranty that the goods will conform to that promise. TEX. BUS. & COM. CODE ANN. § 2.313(a)(1) & (2); *Omni USA, Inc. v. Parker-Hannifin Corp.*, 964 F.Supp.2d 805, 814 (S.D. Tex. 2013). Express warranties may arise from representations made outside of the contracting documents, if the representations form the basis of the bargain. *See, McKay v. Novartis*, 934 F.Supp.2d 898-911-912 (W.D. Tex.

2013) (recognizing that misrepresentations in package insert supported a breach of an express warranty claim distinct from a failure to warn claim); see also, *PPG Indus., Inc. v. JMB/Houston Centers Partners Ltd. Partnership*, 146 S.W.3d 79, 90 (Tex. 2004)(holding that it was a question for the jury whether statements made by the manufacturer in an advertisement in a trade publication created an express warranty). Crucially, “to prevail on a breach of an express warranty claim, the plaintiff must demonstrate that she relied upon the warranty.” *Omni USA, Inc.*, 964 F.Supp.2d at 814 (citing *Am. Tobacco Co.*, 951 S.W.2d at 436).

Plaintiff argues here that there are two discrete express warranties in the documents accompanying the Bravelle medication. The first, according to Tsao, is set out in the Patient Information form included with every package of the drug. She claims the Patient Information Form promises that each lot of Bravelle “contained FSH in sufficient amount and with sufficient potency to treat women who need help developing and releasing eggs. . . .” (Plaintiff’s Complaint at 8). Plaintiff says that she read and relied on this representation before using Defendant’s product. (*Id.*). Plaintiff argues that “the lack of FSH potency levels as stated in the Patient Information Form is the lynchpin of her claims.” (Plaintiff’s Objections to Magistrate Judge Mary Milloy’s Memorandum and Recommendation on Ferring’s Motion to Dismiss at 4). However, the Patient Information does not support Tsao’s claim, because it does not contain the “warranty” that she alleges. The Patient Information form states only that Bravelle “contains follicle stimulating hormone (FSH).” It makes no express statements regarding the effectiveness or sufficiency of the medication. Even the most strained reading of the document fails to uncover any sentence that warrants that each vial or lot of Bravelle contains FSH in “sufficient amount and with sufficient potency” to treat women, as Plaintiff alleges. The Patient Information Form additionally states that dosing levels will be set and

adjusted by the treating physician, and may require more than one vial, which is contrary to any inference that any individual vial or lot is “a sufficient amount.” For this reason, Plaintiff has failed to clear even the minimal hurdle of identifying an actual statement made by Ferring, in the Patient Information form, from which a breach of an express warranty claim can arise. *See, e.g., Melder v. Morris*, 27 F.3d 1097, 1101-1102 (5th Cir. 1994) (dismissing fraud claim when plaintiffs failed to base the allegations on statements *actually* made by the defendant).

**The second warranty claimed by Tsao is said to be found in the Prescribing Information, which states that Bravelle contained “82.5 International Units of FSH, to deliver 75 International Units FSH after reconstituting.” (*Id.*). Tsao’s complaint about this statement rests on firmer ground, because the Prescribing Information does, in fact, include that language. Plaintiff alleges that she relied on the statements in the Prescribing Information in making the decision to use Bravelle. (Plaintiff’s Complaint at 8). The court must accept the contention that she relied on that statement as part of the reason for her transaction with Defendant. As discussed earlier, Plaintiff has alleged that the medicine did not work for her, and that she suffered economic harm from purchasing the ineffective medicine. In that regard, Tsao has stated a claim for a breach of the express warranty contained in the Prescribing Information.**

*C. DTPA Claims*

Plaintiff’s remaining cause of action is that Ferring violated the DTPA by using or employing “false, misleading, or deceptive acts or practices.” *See*, TEX. BUS. & COMM. CODE ANN.

§17.50(a)(1).<sup>2</sup> The statute enumerates various, nonexclusive, conduct that can constitute false, misleading, or deceptive practices—the so-called “laundry list violations” contained in § 17.46(b). *See* TEX. BUS. & COM. CODE ANN. § 17.50(a)(1)(A). Tsao maintains that Ferring’s representations about its product were untrue and violated four specific provisions of the DTPA:

- 1) representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have . . . 17.46(b)(5);
- 2) representing that goods or services are of a particular standard, quality, or grade . . . 17.46(b)(7);
- 3) advertising goods or services with intent not to sell them as advertised . . . 17.46(b)(9);
- 4) failing to disclose information concerning goods or services which was known at the time of the transaction if such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed. 17.46(b)(24).

Tsao claims, as well, that these violations were knowing and intentional.

To state a valid claim under the DTPA, Tsao must show that (1) she is a consumer, (2) that the defendant engaged in false, misleading, or deceptive acts, and (3) that those acts were a producing cause of her damages. *See* TEX. BUS. & COM. CODE ANN. § 17.50(a)(1); *see also Hugh Symons Group, plc v. Motorola, Inc.*, 292 F.3d 466, 468 (5th Cir. 2002) (citing *Chamrad v. Volvo Cars of North America*, 145 F.3d 671, 672 n. 3 (5th Cir.1998)), cert. denied, 537 U.S. 950 (2002). For an act to be a producing cause, it must be a substantial factor in bringing about the injury, which would not otherwise have occurred. *Alexander v. Turtur & Associates, Inc.*, 146 S.W.3d 113, 117 (Tex. 2004).

### *1. Misrepresentations*

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<sup>2</sup> Tsao’s Complaint includes claims for a breach of an implied warranty and for a breach of an express warranty under the DTPA warranty provisions. Because those warranty claims have been addressed elsewhere there is no need to repeat that analysis.



Plaintiff contends Ferring's "warranties" falsely advertised the quality and benefits of the drug. It is clear that a defendant's statements can trigger both a breach of a warranty claim, and violate the DTPA. *See, e.g., Khan v. Vesicol Chem. Corp.*, 711 S.W.2d 310, 318 (Tex.App.—Dallas 1986, ref. n.r.e.)(noting that an affirmative representation by a seller that creates an express warranty under the UCC may also constitute false and misleading representations prohibited by the DTPA); *but see, Mills v. Warner-Lambert Co.*, 581 F.Supp.2d 772 (E.D. Tex. 2008)(noting that DTPA and implied warranty claims for selling ineffective medicine were substantively the same for purposes of preemption analysis). A consumer may still have a cause of action under the DTPA even if a statement is insufficient to create a warranty. *Hell Graphic Systems, Inc. v. Kingcraft Color Graphics, Inc.*, 998 F.2d 1013 (5th Cir. 1993)(upholding jury award of DTPA damages and noting the jury did not find a breach of warranty). Likewise, deceptive labeling, package inserts, or advertisements can also form the basis of a DTPA claim. *See, e.g., State v. Valerie Saxion, Inc.*, 450 S.W.3d 602 (Tex.App.—Fort Worth 2014, no pet.)(involving suit for violations of the DTPA and Texas Food, Drug and Cosmetic Act due to false and misleading labels and advertisements of dietary supplements).

"The DTPA protects consumers; therefore, consumer status is an essential element of a DTPA cause of action." *Mendoza v. Am. Nat'l Ins. Co.*, 932 S.W.2d 605, 608 (Tex.App.—San Antonio 1996, no writ) (citation omitted). To qualify as a consumer under the DTPA, one must have purchased goods, and those goods must form the basis of the complaint. *Miller v. BAC Home Loans Servicing, L.P.*, 726 F.3d 717, 724 (5th Cir. 2013); *see also* TEX. BUS. & COM. CODE § 17.45(4) (providing the statutory definition of consumer). Tsao alleges she purchased, and used Bravelle, in reliance on misrepresentations made about the drug. She has also itemized the costs of the drug.

In doing so, she has sufficiently alleged facts supporting her consumer status under the DTPA.

Because Plaintiff's DTPA claims are based on a misrepresentation, however, Federal Rule of Civil Procedure 9(b) requires Plaintiff to allege the particular "time, place and contents" of the misrepresentation, as well as the identity of the person making it. *Tel-Phonic Services, Inc.*, 975 F.2d at 1139. Plaintiff has pointed to the statement in the Prescribing Information that she contends is false, that each vial of Bravelle contains 75 I.U. of FSH. On these facts, Plaintiff has identified the contents of the statement sufficient to satisfy Rule 9(b). *See, Tuchman v. DSC Communications Corp.*, 818 F.Supp. 971, 977 (N.D. Tex. 1993) (citing *Kronfeld v. First Jersey Nat'l Bank*, 638 F.Supp. 1454, 1463 (D. NJ. 1986)).

However, before any misrepresentation can be said to be actionable, it must have induced the purchase. The fact that a false representation may have been made, does not necessarily create liability, if it is learned after the fact. *Amstadt v. Brass Corp.*, 919 S.W.2d 644, 649 (Tex. 1996). Here, Plaintiff's assertions are too vague to meet her burden of specificity under the applicable Rule. **Plaintiff pleads that she relied upon the "promise" contained in the Prescribing Information when deciding to use Bravelle, but has offered no factual claims supporting that conclusory statement.** This is nothing more than a "formulaic recitation of the elements" for a DTPA claim that fails to plead any facts showing that Plaintiff read and relied upon the statement. *Twombly*, 550 U.S. at 555. **Although Plaintiff's bare allegation of reliance is sufficient to state a claim for a breach of an express warranty, it is not sufficient to satisfy the heightened pleading required for a claim of fraud.**<sup>3</sup>

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<sup>3</sup> Plaintiff's complaint contains only two statements regarding the Prescribing Information. First, it contains a statement that Bravelle contains 75 I.U. of FSH after reconstituting. (Plaintiff's Complaint at 46, 79). Second, Plaintiff relied on this statement and it formed the basis of the transaction between her and Defendant. (*Id.*). Plaintiff's argument that it is "impliedly obvious" this information came from her doctors is contrary to the specificity required in fraud

Tsao insists, however, that her “Complaint sufficiently alleges that Plaintiff relied on the FSH level information in the Bravelle Patient Information Form” to establish both a breach of express warranty and the DTPA claims. (Plaintiff’s Objections at 6). While this might be true, if the Patient Information Form actually contained any statements about FSH levels or potency, actually, the Patient Information Form does not, in fact, warrant, promise, or state that Bravelle “contained FSH in sufficient amount and with sufficient potency to treat women who need help developing and releasing eggs.”

In her objection, Plaintiff argues that her complaint sufficiently alleges that she relied on the FSH level information in the Patient Information Form. While her arguments and factual allegations might support a claim based on the statements contained in the Patient Information Form, they do not provide any support for claims based on the statement in the Prescribing Information. In her complaint, Plaintiff has alleged facts sufficient to show that she read and relied on the Patient Information Form, but has failed to identify a false or misleading statement that is actually contained in that document. On the other hand, Plaintiff has identified a statement in the Prescribing Information that may be false, but she has not described any facts to show that she read and relied on it. It is for these reasons that Plaintiff’s allegations do not suffice to state a DTPA misrepresentation claim based on statements made in the Prescribing Information.

2. *Omissions/Failure to Disclose*

Plaintiff has also alleged a violation under the DTPA for Defendant’s failure to “disclose information concerning goods or services which was known at the time of the transaction.”

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claims.

Although Plaintiff does not identify the information which was allegedly withheld, her pleading can be fairly understood to complain that Ferring did not tell her that Bravelle was less potent than advertised. Under DTPA section 17.46(b)(24), the “failure to disclose material information necessarily requires that the defendant have known the information and have failed to bring it to the plaintiff’s attention.” *See Doe v. Boys Clubs of Greater Dallas, Inc.*, 907 S.W.2d 472, 478 (Tex. 1995)(emphasis in original). There must be evidence of an intentional omission of a material fact by a seller for the express purpose of “duping” a consumer. *Sergeant Oil & Gas Co., Inc. v. National Maintenance & Repair, Inc.*, 861 F.Supp. 1351, 1364 (S.D. Tex. 1994).

In this case, Plaintiff has alleged that Ferring was aware of the problems with its product, but failed to inform her, or the public, of those deficiencies, and yet continued to sell it at a profit. Plaintiff also notes that, because of the problems with the drug, Ferring was forced to remove it from the market. Defendant’s conduct must, however, have been a producing cause of Plaintiff’s damages. *Hugh Symons Group, plc*, 292 F.3d at 468. Ferring’s alleged misrepresentations or omissions must have been the “cause in fact” of Tsao’s injury, and she must allege facts that plausibly support that claim. *See, Doe*, 907 S.W.2d at 478. **Similar to her contentions surrounding the alleged false representations, Plaintiff’s allegations that Ferring failed to disclose material information, and that failure was a cause in fact of her injury, do not meet the heightened pleading requirements for a fraud claim. To the extent that Plaintiff seeks recovery for direct or consequential economic damages, she has not alleged facts with sufficient particularity to support her claim that her purchase of Bravelle was induced by omissions in the Prescribing Information or Patient Information Form.**

In addition, Plaintiff seeks recovery for mental anguish due to her failure to bear a child.<sup>4</sup> But, Plaintiff has failed to allege any facts that show she relied on the purported misrepresentation in the Prescribing Information, and so it can not be a producing cause of her mental anguish. Further, even had Plaintiff established reliance, she must still show the misrepresentations or omissions were a producing cause of her mental anguish. Her general claims of mental anguish and statements that she was disappointed at failing to bear a child, without more, do not make a plausible claim that Defendant's statements or omissions about the drug were a producing cause of that disappointment.

### 3. *Treble Damages and Claims for Mental Anguish*

Plaintiff seeks treble damages, as well as mental anguish damages, because of Ferring's alleged knowing and intentional violations of the DTPA. Because Plaintiff seeks recovery for breaches of both express and implied warranties, under the DTPA, the dismissal of the "laundry list" violations does not moot this issue. *See generally, Continental Dredging, Inc. v De-Kaizered, Inc.*, 120 S.W.3d 380, 390 (Tex.App.—Texarkana 2003, pet. denied)(recognizing that breach of warranty and DTPA laundry list violations are separate causes of action); *Indust-Ri-Chem Lab., Inc. v. Par-Pak Co., Inc.*, 602 S.W.2d 282 (Tex.Civ.App.—Dallas 1980, no writ) (upholding treble damage award for breach of warranty under DTPA). Defendant argues that Tsao has failed to plead any facts showing that it "knew" or "intended" to sell her a defective drug. Although scienter may be "averred generally" under Rule 9(b), a plaintiff must still describe specific facts that support an inference of fraud. *DiLeo v. Ernst & Young*, 901 F.2d 624, 629 (7th Cir. 1990) ("Although Rule 9(b)

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<sup>4</sup> See, Plaintiff's Response at 5 ("Plaintiff also pleads for mental anguish damages as a result of undergoing fertility treatment that were destined to fail, experiencing disappointment after crushing disappointment, all the while clinging to the hope that her efforts would yield a baby with all the expectations, happiness, love, and joy that accompanies the birth of a most wanted child.").

does not require ‘particularity’ with respect to the defendants’ mental state, the complaint must still afford a basis for believing that plaintiffs could prove scienter.”) cert. denied, 498 U.S. 941, 111 S.Ct. 347, 112 L.Ed.2d 312 (1990).

In this case, Plaintiff has sufficiently, but very narrowly, alleged intentional conduct by Defendant. Specifically, Plaintiff claims that Defendant knew, for at least part of the relevant time period, that there were problems with its drug, yet it continued to market it. Plaintiff alleges the drug was recalled in October 2015, because of the known problems, but that she purchased drugs from the affected lots during that month. These allegations give rise to a “strong inference” that Ferring sold Bravelle to Plaintiff knowing there was a problem with the product.

*D. Plaintiff’s Request for Leave to Amend*

“The court should freely give leave [to amend the pleadings] when justice so requires.” FED. R. CIV. P. 15(a)(2). The decision whether to permit amendment “is entrusted to the sound discretion of the district court.” *Wimm v. Jack Eckerd Corp.*, 3 F.3d 137, 139 (5th Cir. 1993). Nevertheless, the Fifth Circuit has commented that the term “discretion” “may be misleading because FED. R. CIV. P. 15(a) evinces a bias in favor of granting leave to amend.” *Mayeaux v. Louisiana Health Serv. & Indemn. Co.*, 376 F.3d 420, 425 (5th Cir. 2004)(citation omitted). “[A]bsent a ‘substantial reason’ such as undue delay, bad faith, dilatory motive, repeated failures to cure deficiencies, or undue prejudice to the opposing party, ‘the discretion of the district court is not broad enough to permit denial.’” *Id.* (citation omitted).

If a plaintiff’s complaint fails to state a claim, the court should generally give her at least one chance to amend it under Rule 15(a), before dismissing the action with prejudice. *Great Plains Trust Co v. Morgan Stanley Dean Witter & Co.*, 313 F.3d 305, 329 (5th Cir. 2002)(“District courts

often afford plaintiffs at least one opportunity to cure pleading deficiencies before dismissing a case, unless it is clear that the defects are incurable or the plaintiffs advise the court that they are unwilling or unable to amend in a manner that will avoid dismissal.”); *United States ex rel. Adrian v. Regents of the Univ. of Cal.*, 363 F.3d 398, 403 (5th Cir. 2004)(“Leave to amend should be freely given, and outright refusal to grant leave to amend without a justification . . . is considered an abuse of discretion.”).

In her Response to Defendant’s motion, Plaintiff has asked to amend her Complaint, if it is determined to be insufficient to survive the motion to dismiss. **It is recommended that Plaintiff be permitted to amend her Complaint with respect to her claims for the DTPA “laundry list violations.”** However, it appears impossible for Plaintiff to state a claim for relief for a breach of the implied warranty of fitness for a particular purpose. Because that deficiency is incurable, it is recommended that that claim be dismissed with prejudice.

### **CONCLUSION**

After reviewing Plaintiff’s Complaint, Defendant’s Motion, and Plaintiff’s Response, it is **RECOMMENDED** that Defendant’s Motion to Dismiss be **GRANTED IN PART** and **DENIED IN PART**, as follows:

Defendant’s Motion to Dismiss Plaintiff’s claims for breach of implied warranty of merchantability is **DENIED**;

Defendant’s Motion to Dismiss Plaintiff’s claim for breach of implied warranty of fitness for a particular purpose is **GRANTED** with prejudice;

**Defendant’s Motion to Dismiss Plaintiff’s claims for breach of express warranty, whether pursuant to common law or statute, is DENIED;**

Defendant's Motion to Dismiss Plaintiff's violations of sections 17.46(b)(5), (b)(7), (b)(9), and (b)(24) of the Texas Business & Commerce Code is **GRANTED** without prejudice; and

Defendant's Motion to Dismiss Plaintiff's claim for treble or mental anguish damages is **DENIED**;

Plaintiff is **GRANTED** Leave to Amend her Complaint, and is ordered to file any such Amendment within thirty days.

The Clerk of the Court shall send copies of the Memorandum and Recommendation to the respective parties, who will then have fourteen days to file written objections, pursuant to 28 U.S.C. § 636(b)(1)(c), General Order 02-13, S.D. Texas. Failure to file written objections within the time period provided will bar an aggrieved party from attacking the factual findings and legal conclusions on appeal.

The original of any written objections shall be filed with the United States District Clerk, P.O. Box 61010, Houston, Texas, 77208; copies of any such objections shall be delivered to the chambers of Vanessa D. Gilmore, Room 9513, and to the chambers of the undersigned, Room 7007.

**SIGNED** at Houston, Texas, this 4th day of January, 2017.

A handwritten signature in black ink, appearing to read 'Mary Milloy', is centered on the page.

**MARY MILLOY**  
**UNITED STATES MAGISTRATE JUDGE**